



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-1131]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; New Animal Drug Applications and Supporting Regulations and Form FDA 356V

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0032. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796, 3794, Jonnalynn.capezzuto@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Presubmission Conferences, New Animal Drug Applications and Supporting Regulations and Guidance #152, and Form FDA 356V--21 CFR 514.5, 514.1, 514.4, and 514.8 (OMB Control Number 0910-0032)--Extension

Under section 512(b)(3) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360b(b)(3)), any person intending to file a new animal drug application (NADA) or supplemental NADA or a request for an investigational exemption under section 512(j) of the FD&C Act is entitled to one or more conferences with FDA to reach an agreement acceptable to FDA establishing a submission or investigational requirement. FDA and industry have found that these meetings have increased the efficiency of the drug development and drug review processes.

Section 514.5 of Title 21 of the Code of Federal Regulations describes the procedures for requesting, conducting, and documenting presubmission conferences. Section 514.5(b) describes the information that must be included in a letter submitted by a potential applicant requesting a presubmission conference, including a proposed agenda and a list of expected participants. Section 514.5(d) describes the information that must be provided by the potential applicant to FDA at least 30 days prior to a presubmission conference. This information includes a detailed agenda, a copy of any materials to be presented at the conference, a list of proposed indications and, if available, a copy of the proposed labeling for the product under consideration, and a copy of any background material that provides scientific rationale to support the potential applicant's position on issues listed in the agenda for the conference. Section 514.5(f) discusses the content of the memorandum of conference that will be prepared by FDA and gives the potential applicant an opportunity to seek correction to or clarification of the memorandum.

Under section 512(b)(1) of the FD&C Act, any person may file a NADA seeking approval to legally market a new animal drug. Section 512(b)(1) sets forth the information required to be submitted in a NADA. FDA allows applicants to submit a complete NADA or to submit information in support of a NADA for phased review followed by submission of an administrative NADA when FDA finds all the applicable technical sections are complete.

Section 514.1 of Title 21 of the Code of Federal Regulations interprets section 512(b)(1) of the FD&C Act and further describes the information that must be submitted as part of a NADA and the manner and form in which the NADA must be assembled and submitted. The application must include safety and effectiveness data, proposed labeling, product manufacturing information, and where necessary, complete information on food safety (including microbial food safety) and any methods used to determine residues of drug chemicals in edible tissue from food producing animals. Guidance #152 outlines a risk assessment approach for evaluating the microbial food safety of antimicrobial new animal drugs. FDA requests that an applicant accompany NADAs, supplemental NADAs, and requests for phased review of data to support NADAs, with the Form FDA 356V to ensure efficient and accurate processing of information to support new animal drug approval.

In the Federal Register of November 20, 2012, (77 FR 69630), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

Table 1.--NADAs--Estimated Annual Reporting Burden¹

21 CFR Section/FDA Form No.	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
514.5(b), (d), (f) Requesting presubmission conferences	169	0.41	69	50	3,450
514.1 and 514.6 Applications and amended applications	169	0.07	12	212	2,544
514.8(b) Manufacturing changes to an approved application	169	2.22	375	35	13,125
514.8(c)(1) Labeling and other changes to an approved application	169	0.06	10	71	710
514.8(c)(2) and (3) Labeling and other changes to an approved application	169	0.72	121	20	2,420
514.11 Submission of data, studies and other information	169	0.08	14	1	14
558.5(i) Requirements for liquid medicated feed	169	0.01	1.7	5	8.5
514.1(b)(8) and 514.8(c)(1) ² Evidence to establish safety and effectiveness	169	0.15	25	90	2,250
Form FDA 356V	169	4.37	739	5	3,695
Total					28,217

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

² NADAs and supplements regarding antimicrobial animal drugs that use a recommended approach to assessing antimicrobial concerns as part of the overall preapproval safety evaluation.

Based on the number of sponsors subject to animal drug user fees, FDA estimates that there was an average of 169 annual respondents during the 5 fiscal years, from October 1, 2008, through September 30, 2012, on which these estimates were made. We use this estimate

consistently throughout the table and calculate the "total annual responses" by multiplying the number of responses per respondent by the number of respondents.

Dated: May 7, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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